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EXAMINER	
KUMAR, VINOD	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,648	AN ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) *1-36,41-49 and 59-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-40 and 50-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group III, claims 37-40, 50-58 and SEQ ID NOs: 29 and 63, and species ammonium transporter and 1c-109-35 in the paper filed July 17, 2006 is acknowledged.

Applicants argue that there is not an undue burden placed upon the Examiner to search and consider all of the claims (response, page 2, lines 15-19).

Applicant's argument filed was fully considered but is not found persuasive. Examiner maintains that inventions I-VIII are patentably distinct and would result in undue search burden if examined together for the reasons of record stated in the Office action mailed June 14, 2006.

Accordingly, claims 1-36, 41-49, 59-66, and SEQ ID NOs: 1-28, 30-62, 64-68, and species AOX1a, XA21-like protein kinase, receptor-like protein kinase, MMSDH1, homolog of the RNA-binding protein LAH1, vacuolar ATP synthase subunit X, cinnamic acid 4-hydroxylase, H-protein promoter binding factor-2a, FEN-1, Hsp70, ATP-dependent RNA helicase, glucose-6-phosphate/phosphate transporter, RNA methyltransferase, actin depolymerizing factor 5, beta-glucosidase for claim 37, and 1b-115-22, 1b-164-43, 1b-192-40, 1b-207-27, 1b-138-07, 1d-059-12, 1c-087-40, 1c017-14, 1c-038-56, 1c041-47, 1c-064-20, 1c-109-51, 1c-056-07, 1c-100-32, 1c-142-27, 1c-140-04 for claim 40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Non-elected subject matter must be removed from the elected claims. Claims 37-40, 50-58 in conjunction with SEQ ID

NOs: 29 and 63, and species ammonium transporter and 1c-109-35 are examined on merits in the instant Office action. This restriction is made FINAL.

Applicant are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed 5/10/2005 is attached to the instant Office action.

Priority

3. It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/427,166, filed 11/15/2002. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four

months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference

was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Objections

4. Claims 37-40 and 50-58 are objected to because of the following informalities:

In claims 37-39, line 1, replace "a" after "wherein" and before "gene" with --an endogenous--.

In claim 40, insert --, wherein said rice plant comprises a T-DNA disrupted SEQ ID NO: 29 at the end of claim. Also, replace "modified" with --transformed--.

Claim 50-54 are objected to for depending from non-elected claim.

In claims 50 and 51, line 3, replace "an" after "comprising" and before "amino acid" with --the--.

In claim 52, line 2, replace "a" after "comprises" and before "nucleotide sequence" with --the--.

In claims 56-58, line 3, replace "an" after "to" and before "amino acid" with --the--.

In claims 37-40 and 50-58 non-elected subject matter should be deleted.

Appropriate action/corrections are required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 37-39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 37-39 read on a genetically modified rice plant per se. The genetically modified rice plant is found in nature and thus, is unpatentable to Applicant. A genetically modified rice plant can be naturally produced through naturally occurring non-homologous recombination between non-homologous gene sequences of a plant genome that may not be related, and thereby creating gene disruption(s). A genetically modified rice plant can also be produced through natural gene mutation(s) resulting in gene disruption. The genetically modified rice plant of claims 37-39 has the same characteristics as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). It is suggested that claims be amended by replacing "modified" with --transformed--, and inserting --, wherein said disruption comprises a T-DNA insert-- at the end of claims to identify a product that is not found in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in its recitation "disrupted", which is confusing since it is unclear what is being disrupted. Is it gene structure or function or both that are disrupted? Is it the coding or non-coding nucleotide sequence of the gene that is disrupted? Specification does not define the recitation.

Appropriate action/clarifications are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 37-40 and 50-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a genetically transformed rice plant comprising disruption of a nucleotide sequence (SEQ ID NO: 29) encoding SEQ ID NO: 63 due to the insertion of a T-DNA sequence in said nucleotide sequence, or a transgenic plant comprising transformation of said plant with a nucleotide sequence encoding a polypeptide sequence of SEQ ID NO: 63, does not reasonably provide enablement for a) a genetically transformed rice plant comprising disruption of any gene encoding any ammonium transporter by any method, b) a genetically transformed rice

plant comprising disruption of a nucleotide sequence (SEQ ID NO: 29) encoding SEQ ID NO: 63 by a method other than T-DNA insertion of said nucleotide sequence, c) a transgenic plant comprising transformation with a nucleotide sequence encoding a polypeptide which has less than 100% sequence identity with SEQ ID NO: 63. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims are broadly drawn to a genetically modified rice plant comprising a ammonium transporter gene which has been disrupted, or a genetically modified plant comprising transformation of said plant with a nucleic acid sequence encoding a polypeptide of SEQ ID NO: 63.

The specification teaches a transgenic rice plant 1c-109-35 produced by transformation of rice plant with a gene trap vector comprising T-DNA inserts, wherein T-DNA insert comprises a promoterless *GUS* reporter gene that encodes the enzyme β-glucuronidase (GUS). The transgenic rice plant 1c-109-35 carried the T-DNA insert in an ammonium transporter genomic sequence (SEQ ID NO: 29) which encodes SEQ ID NO: 63. Furthermore, specification teaches pollen-specific expression characteristics and T-DNA insertion of tagged line 1c-109-35. See Figures 1, 2, 14A, 14B; pages 71-73, paragraphs 00323-00327.

Claim 37 encompasses a genetically modified rice plant comprising disruption of any ammonium transporter gene, claims 38-40 encompasses a genetically modified rice plant comprising disruption of a nucleotide sequence of SEQ ID NO: 29 which encodes an ammonium transporter polypeptide as defined in SEQ ID NO: 63. The specification

provides guidance on a method of making a T-DNA tagged transgenic rice plant (1c-109-35) comprising transformation of said rice plant with a gene trap vector comprising T-DNA insert, wherein T-DNA is inserted in the genomic sequence of a gene encoding ammonium transporter as defined in SEQ ID NO: 63. But specification does not provide guidance on making a genetically modified plant comprising disruption of any ammonium transporter gene or SEQ ID NO: 29 by a method other than transforming a rice plant with a gene trap vector comprising T-DNA insert. Undue experimentation would have been required by a skilled artisan to determine how to make a genetically modified rice plant comprising disruption of a rice ammonium transporter gene or SEQ ID NO: 29 by a method other than transforming said rice plant with a gene trap vector comprising T-DNA insert.

Claim 37 encompasses disruption of any ammonium transporter gene of a rice plant. The specification provides guidance on a method of making a T-DNA tagged transgenic rice plant (1c-109-35) comprising transformation of said rice plant with a gene trap vector comprising T-DNA insert, wherein T-DNA is inserted in the genomic sequence of a gene encoding ammonium transporter as defined in SEQ ID NO: 63. Hoque et al. (Functional Plant Biology, 33:153-163, 2006) teach that at least 10 ammonium transporter genes have been identified in rice. Some of these are constitutively expressed whereas others exhibit tissue-specific expression. This implies that each of these ammonium transporters may have specific function within the rice plant. Undue experimentation would have been required by a skilled artisan to determine how to disrupt a specific ammonium transporter in the rice genome to obtain a desired phenotype without disrupting other ammonium transporter(s).

Claim 50 encompasses a genetically modified plant comprising increasing expression of a nucleic acid sequence encoding a polypeptide which has at least 90% sequence identity to SEQ ID NO: 63. Further, claim 51 encompasses a genetically modified plant comprising increasing expression of a nucleic acid sequence encoding a polypeptide which has at least 95% sequence identity to SEQ ID NO: 63. Furthermore, claim 55 encompasses a genetically modified seed comprising a nucleic acid sequence encoding a polypeptide which has at least 80% sequence identity to SEQ ID NO: 63. Furthermore, claim 56 encompasses a genetically modified seed comprising a nucleic acid sequence encoding a polypeptide which has at least 80% sequence identity to SEQ ID NO: 63. Furthermore, claims 57 and 58 encompasses a genetically modified seed comprising a nucleic acid sequence encoding a polypeptide which has at least 90% and 95% sequence identity to SEQ ID NO: 63, respectively. This implies that these claims encompass genetically modified plants or seeds comprising a nucleic acid sequence encoding a polypeptide which has less than 100% sequence identity to the ammonium transporter protein as defined in SEQ ID NO: 63. The specification provides a guidance on a method of using a transgenic plant comprising transformation and expression of SEQ ID NO: 29 encoding SEQ ID NO: 63 in said transgenic plant. For example, specification provides guidance that pollen-specific overexpression of SEQ ID NO: 29 can be used in making a transgenic plant with increased nitrogen uptake to enhance pollen tube growth and subsequent fertilization rates (page 73, paragraph 00327). The specification does not provide guidance on a method of using a genetically transformed plant or seed comprising a nucleotide sequence encoding a polypeptide which has less than 100% sequence identity to SEQ ID NO: 63.

It is well established in the art that proteins with similar structure may have different functions. See Keskin et al. (Protein Science, 13:1043-1055, 2004). Besides, Thornton et al. (Nature structural Biology, structural genomics supplement, November 2000) teach that structural data may carry information about the biochemical function of the protein. Its biological role in the cell or organism is much more complex and actual experimentation is needed to elucidate actual biological function under *in vivo* conditions. Furthermore, Guo et al. (PNAS, 101: 9205-9210, 2004) teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as a protein comprising an amino sequence identity of at least 80-95% to SEQ ID NO: 63 would encompass more than a single amino acid changes of the protein defined in SEQ ID NO: 63. Thus, it would have been highly unpredictable to make use of a transgenic plant or its seed comprising a nucleic acid sequence encoding a polypeptide which has less than 100% sequence identity to SEQ ID NO: 63. Neither the state of prior art nor the specification provide guidance on which region(s) of SEQ ID NO: 63 is able to tolerate deletions, additions or substitutions of one or more amino acid without abrogating ammonium transporter activity when expressed in a transgenic plant or seed. The claims encompass inoperable embodiments but the specification provided no guidance as to how such inoperable embodiments can be readily eliminated without undue experimentation. In the absence of guidance, undue experimentation would have been required by one skilled in the art determine how to use a genetically modified plant or seed comprising transformation and expression of a nucleic acid sequence encoding a polypeptide which has less than 100% sequence identity to SEQ ID NO: 63.

See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Claims 50-54 encompasses a genetically modified plant comprising decreasing the expression of a nucleic acid sequence encoding a polypeptide which has at least 90-100% sequence identity to SEQ ID NO: 63. Applicants provide a generalized guidance on using antisense or cosuppression based approach of decreasing the expression of SEQ ID NO: 29 encoding SEQ ID NO: 63. Antisense suppression of gene expression is highly unpredictable, and the prior art suggests that success depends on the % identity between the sequence of the antisense construct and the target gene sequence (see Elomaa et al. (1996) Molecular Breeding, Vol. 2, pp. 41-50; paragraph bridging pages 47-48, in particular). In the prior art, Klee et al. teach that antisense genes would probably be species-specific, and therefore a different antisense gene would be required for each species of plant desired to be transformed (see US Patent # 5,702,933, issued Dec. 30, 1997, column 1 lines 60-65, in particular). Likewise, unpredictability of cosuppression based on post transcriptional gene silencing has been extensively reviewed. For example, see Bruening (PNAS, 95:13349-13351, 1998). Applicant's attention is also drawn to last paragraph bridging the pages 72-73, wherein the specification describes that pollen-specific knock-out of the ammonium transporter gene expression by antisense expression of said transporter can be used in creating male-sterile plants. However, neither the prior art nor the specification provide guidance on making said male-sterile plants through decreasing the expression of said ammonium transporter. In the absence of guidance, undue experimentation would have

been required by a skilled artisan to determine how to use a genetically modified plant comprising decreasing the expression of an ammonium transporter (SEQ ID NO: 29) encoding SEQ ID NO: 63 to produce an expected or altered phenotype as encompassed by the claims.

Claims 55-58 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Product that is critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Claim 55 does not mention expressing a nucleic acid sequence encoding the polypeptide that makes seed genetically modified.

Given the breadth of the claims encompassing, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use of claimed invention.

8. Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel biological materials, specifically the genetically modified rice plant 1c-109-35. Since the biological materials are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the biological materials are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by

a deposit of the biological materials. The specification does not disclose a repeatable process to obtain the biological materials and it is not apparent if the biological materials are readily available to the public. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific biological materials have been deposited under the Budapest Treaty and that the biological materials will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the

specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination." The specification should be amended to include this information, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information. Finally, Applicant is advised that the address for the ATCC has recently changed, and that the new address should appear in the specification. The new address is:

American Type Culture Collection

10801 University Boulevard

Manassas, VA 20110-2209

9. Claims 37 and 50-51 and 55-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are broadly drawn to a genetically modified rice plant comprising a ammonium transporter gene which has been disrupted, or a genetically modified plant comprising transformation of said plant with a nucleic acid sequence encoding a polypeptide of SEQ ID NO: 63.

The specification describes a transgenic rice plant 1c-109-35 produced by transformation of rice plant with a gene trap vector comprising T-DNA inserts, wherein T-DNA insert comprises a promoterless *GUS* reporter gene that encodes the enzyme β-glucuronidase (GUS). The transgenic rice plant 1c-109-35 carried the T-DNA insert in

an ammonium transporter genomic sequence (SEQ ID NO: 29) which encodes SEQ ID NO: 63. Furthermore, specification teaches pollen-specific expression characteristics and T-DNA insertion of tagged line 1c-109-35. See Figures 1, 2, 14A, 14B; pages 71-73, paragraphs 00323-00327.

Claim 37 encompasses a genetically modified rice plant comprising disruption of any ammonium transporter gene, claim 50 encompasses a genetically modified plant comprising increasing expression of a nucleic acid sequence encoding a polypeptide which has at least 90% sequence identity to SEQ ID NO: 63. Further, claim 51 encompasses a genetically modified plant comprising increasing expression of a nucleic acid sequence encoding a polypeptide which has at least 95% sequence identity to SEQ ID NO: 63. Furthermore, claim 55 encompasses a genetically modified seed comprising a nucleic acid sequence encoding a polypeptide which has at least 80% sequence identity to SEQ ID NO: 63. Furthermore, claim 56 encompasses a genetically modified seed comprising a nucleic acid sequence encoding a polypeptide which has at least 80% sequence identity to SEQ ID NO: 63. Furthermore, claims 57 and 58 encompasses a genetically modified seed comprising a nucleic acid sequence encoding a polypeptide which has at least 90% and 95% sequence identity to SEQ ID NO: 63, respectively. This implies that these claims encompass genetically modified plants or seeds comprising a nucleic acid sequence encoding a polypeptide which has less than 100% sequence identity to the ammonium transporter protein as defined in SEQ ID NO: 63. The specification does not have adequate written description for the genus of sequences which have at least 80-95% sequence identity to SEQ ID NO: 63, genus of amino transporter genes under current written description guidelines. Specification

does not describe any of these undisclosed structures and one skilled in the art cannot reliably predict the structure of these sequences based upon the disclosure of SEQ ID NOs: 29 and 63.

Furthermore, Applicants have failed to correlate the structures of their broadly claimed genus to the function. Further, Applicants have failed to describe conserved functional domains that are shared by these undisclosed structures encompassed by their broadly claimed genus. The specification does not reduce their broadly claimed genus to practice.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

> granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 55-57 are rejected under 35 U.S.C. 102(a)/102(e) as being anticipated by Allen et al. (US Patent Publication No. 2002/0142390 A1, Filed December 28, 2001, Published October 3, 2002).

Allen et al. disclose a genetically transformed or modified plant comprising transformation of said plant with an expression cassette comprising a nucleic acid sequence encoding a protein as set forth in SEQ ID NO: 14 (ammonium transporter) which is 90% identical in amino acid sequence to instant SEQ ID NO: 63. The reference further teaches increase or decrease of expression of said nucleic acid in said transgenic plant and embryos (seed tissue). The increase in ammonium transporter activity comprised overexpression of said nucleic acid, whereas decrease in ammonium transporter activity comprised cosuppression of said nucleic acid in the transgenic plant or seed, or wherein said genetically modified plant is a monocotyledonous or dicotyledonous plant. See paragraphs 007-0047; 0048-0061; pages 8-12, examples 1-8.

Accordingly, Allen et al. anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 37-40 are Claims 50-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buell et al. (EMBL/GenBank/DDBJ databases, Sequence Accession No. Q851M9 Published December 2001) in view of Jeon et al. (The Plant Journal, 22:561-570, 2000).

Buell et al. teach a recombinant DNA construct (contig) comprising a nucleic acid sequence from rice encoding a ammonium transporter which has 100% sequence identity to instant SEQ ID NO: 63.

Buell et al. do not teach a method of disrupting a gene.

Jeon et al. teach a method of disrupting rice genes using T-DNA insertional mutagenesis. Reference further teaches T-DNA-tagged lines are useful in identifying insertional mutants in various genes and for discovering new genes in rice. See in particular, page 561, abstract; page 569, experimental procedure.

It would have been obvious for one of the ordinary skill in the art to disrupt Buell et al. nucleic sequence encoding an ammonium transporter by producing a T-DNA tagged line of rice plant using any method of gene disruption including the one taught by Jeon et al. It would have been obvious to use gene-specific probe for the ammonium transporter gene derived from Buell et al. teachings to identify T-DNA tagged line of rice comprising disruption in said ammonium transporter gene. Given that Jeon et al. teach the usefulness of using T-DNA mutagenesis based approach for studying gene function, one of the ordinary skill in the art would have been motivated to produce a transgenic plant comprising disrupted ammonium transporter gene to study its specific function in the rice plant.

Thus, the claimed invention as a whole was prima facie obvious over the combined teachings of the prior art.

12. Claims 50-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buell et al. (EMBL/GenBank/DDBJ databases, Sequence Accession No. Q851M9 Published December 2001) in view of Valvekens et al. (PNAS, 85:5536-5540, 1988), and Howitt et al. (Biochimica et Biophysica Acta, 1465:152-170, 2000).

Buell et al. teach a recombinant DNA construct (contig) comprising a nucleic acid sequence from rice encoding a ammonium transporter which has 100% sequence identity to instant SEQ ID NO: 63.

Buell et al. do not teach a method of producing a transgenic plant or seed.

Valvekens et al. teach a method of transformation of plant cells and regeneration of transgenic plant and F1 segregating population obtained from seeds of said transgenic plant expressing heterologous protein. See page 5536, column second through column 1 of page 5537; page 5538, Figures 3 and 4.

Howitt et al. teach that ammonium is one of the principal sources of nitrogen for plant growth in agriculture, and ammonium transporters in plants are involved in uptake of nitrogen in the form of ammonium and distribute it to the sites of consumption. Furthermore, modifying the ammonium transport system in a plant would reduce reliance on fertilizer nitrogen which will benefit not only farmers, but also the environment. See the entire article.

It would have been obvious for one of the ordinary skill in the art to use Buell et al. nucleic sequence encoding the ammonium transporter, in a method of producing a

transgenic plant and seed using any method of plant transformation including the one taught by Valvekens et al. It would have been obvious for one of the ordinary skill in the art to have been motivated to express Buell et al. nucleic acid sequence in a plant to produce a transgenic plant overexpressing said ammonium transporter. Given that Howitt et al. teach that ammonium transporters are involved in growth improvement in a plant through nitrogen uptake, one of the ordinary skill in the art would have been motivated to produce a transgenic plant expressing Buell et al. ammonium transporter for the purpose of improving growth and thereby increase the yield of said transgenic plant.

Thus, the claimed invention as a whole was prima facie obvious over the combined teachings of the prior art.

Conclusions

13. Claims 37-40 and 50-58 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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